September 5, 2025

Prytime Medical Devices, Inc.
Jeanette Losole
Senior Quality Engineer
12 Upper Balcones Rd.
Boerne, Texas 78006

Re: K243795
Trade/Device Name: pREBOA-PRO Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: August 6, 2025
Received: August 6, 2025

Dear Jeanette Losole:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rohini Retarekar -S

for Carmen Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243795

Device Name
pREBOA-PRO Catheter

Indications for Use *(Describe)*
The pREBOA-PRO Catheter is intended for temporary partial or complete occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K243795

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Company:	Prytime Medical Devices, Inc. 12 Upper Balcones Rd. Boerne, TX 78006
Contact:	Jeanette Losole Sr Quality Engineer Prytime Medical Devices, Inc. Tel: (210) 262-9950 FAX: (210) 558-1860 Email: jlosole@prytimemedical.com

Date Summary Prepared:	September 5, 2025

Name of the Device:

Trade Name:	pREBOA-PRO™ Catheter
Common Name:	Occlusion balloon catheter
Classification Name:	Catheter, Intravascular Occluding, Temporary
Review Panel:	Cardiovascular (CV)
Regulation:	870.4450, 870.1250, 870.1200
Class:	II
Product Code:	MJN, DQY, DQO

Submission Type: Traditional 510(k)

Predicate device:

pREBOA-PRO Catheter cleared under 510(k) number K200459.

Device Description

The pREBOA-PRO™ Catheter is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring. The device consists of a semi-compliant balloon, in-line pressure relief valve (safety valve), atraumatic distal tip (P-tip™), dual lumen catheter shaft and a hub with extension lines to provide access to each lumen.

The pREBOA-PRO™ Catheter is designed with flow channels to enable precise, smooth control of inflation and deflation of the balloon. Instructions for how to titrate the balloon for partial occlusion, if so desired by the clinician, are included in the Instructions for Use.

The device has an effective length of 72 cm and is compatible with 7 Fr introducer sheaths as shown in the compatibility section of the IFU. The catheter has a unibody design and is intended to be placed and advanced without a guidewire. In addition, the catheter is compatible with guidewires up to 0.025" that may be used to facilitate subsequent vascular procedures after a REBOA procedure. An orange peel-away sheath is preloaded on the catheter shaft covering the balloon to ease insertion of the catheter's P-tip™ into an introducer sheath hemostasis valve. A catheter shaft provides appropriate stiffness with a distal tip (P-tip™) designed for atraumatic advancement of the catheter in a blood vessel. Pad printed marks on both sides of the outer catheter shaft indicate distance to the center of the balloon as well as average insertion depth ranges to the center of aortic Zones 1 and 3 to facilitate proper placement. Radiopaque platinum iridium marker bands are located at the functional ends of the balloon to facilitate and visualize accurate balloon placement when used with imaging. The proximal end of the catheter has a hub and extension lines. The arterial line lumen is used to monitor blood pressure above the balloon. Below the balloon core aortic pressure monitoring is possible through the side arm of the sheath. The balloon lumen is used to inflate and deflate the balloon as needed. An in-line safety valve is connected to the balloon lumen stopcock and is designed to help prevent over-inflation of the balloon. The stopcocks provide control to each of the catheter's two lumens. The orange peel-away sheath can be separated from the catheter shaft after insertion if needed. The device is a single-use, sterile device.

Indications for Use

The pREBOA-PRO™ Catheter is intended for temporary partial or complete occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

Comparison with the Predicate Device

The modified pREBOA-PRO™ Catheter is identical to the predicate unmodified device with the exception of the Instructions for use which have been modified as follows:

- Indication for Use statement has been modified to include clarifying text regarding the degree of occlusion (partial or complete)
- Labeling is modified to include above and below the balloon core aortic blood pressure reference values.
- Added precaution statement regarding available data on maximum complete and partial occlusion durations.

Performance Data

A consensus algorithm based on limited clinical data and experience[1] combined with multiple swine studies[2,3,4] using pREBOA-PRO Catheter have provided learnings to clinicians about partial occlusion blood pressures and occlusion durations. The key finding in the swine studies

regarding distal ischemia was that at 2 hours of partial occlusion in Zone 1, with below balloon systolic blood pressure (SBP) of 20 mmHg and pulsatile flow, there were no physiological impacts below the balloon that would require surgical intervention. In contrast, clinical guidelines[5] have established that increased caution should be exercised when *complete* aortic occlusion times approach 30 minutes in Zone 1 and 60 minutes in Zone 3.

Bench test results demonstrated that the pREBOA-PRO Catheter was able to achieve and maintain targeted below balloon blood pressure ($\geq$ 20 mmHg) for partial occlusion for a duration of 2 hours. Additionally, the bench testing demonstrated that the device could maintain partial occlusion after being subjected to simulated positive and negative physiological disturbances (i.e. changes in heart rate and aortic diameter) which are typical during severe shock and on-going resuscitation.

Conclusions

Available evidence supports that the pREBOA-PRO™ Catheter is substantially equivalent with the predicate.

References

1. Nguyen J, Spalding MC, Meyer CH, Beckett A, Smith A, Kundi R, Raza SS, Radomski M, Dennis B, Mukherjee K, Akrish E, Raley J, Fox C, Moore EE. A DELPHI CONSENSUS ALGORITHM FOR MODERN REBOA PROGRAMS: EMPLOYING A TITRATABLE CATHETER AND PARTIAL AORTIC OCCLUSION TO ADVANCE THE PROCEDURE. Shock. 2025 Aug 1;64(2):176-186. doi: 10.1097/SHK.0000000000002622. Epub 2025 Apr 30. PMID: 40341373.

2. Kemp et. al., A Novel Partial Resuscitative Endovascular Balloon Aortic Occlusion (pREBOA) Device That Can Be Deployed in Zone 1 for more than 2 hours with Minimal Provider Titration, J Trauma Acute Care Surg. 2020; 90(3): 426-433

3. Ho et. al., Prolonging the zone 1 aortic occlusion time to 4 hours using a partial resuscitative endovascular balloon in a swine model, J Trauma Acute Care Surg. 2023; 95(S2): S129-S136

4. Ho et. al., Finding the right balance: Partial REBOA in a swine model of uncontrolled vascular injury, J Am Coll Surg. 2024 Jan 1;238(1):32-40

5. J. Glaser, Stigall, K., Cannon, J., Jensen, S., Morrison, J. J., Snyder, S., Russo, R., Manley, J., Becker, T., Dubose, J., Rasmussen, T., Graybill, J., Gurney, J., & Shackelford., S, Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock (CPG ID:38), (2020)